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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,680	05/26/2000	Blake R. Pepinsky	BIJ-P02-067	8259

28120 7590 12/05/2001

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BOSTON, MA 02110-2624

EXAMINER
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O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/05/2001

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/579,680

Applicant(s)

PEPINSKY ET AL.

Examiner

Eileen B. O'Hara

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-86 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-18, 28-33, 48, 62, 66, 67 and 74-85, drawn to proteins appended with hydrophobic moieties, classified in class 350, subclass 402.
  - II. Claims 19-27, drawn to proteins comprising spacers, classified in class 530, subclass 350, for example.
  - III. Claims 34-39, drawn to a method of generating a multivalent protein complex, classified in class 530, subclass 402.
  - IV. Claims 40-46, 50-59, 63-65, 68-73, drawn to a method for modifying a protein to enhance biological activity, by reacting the N-terminal cysteine with compounds to produce a hydrophobic moiety, classified in class 530, subclass
  - V. Claims 47 and 49, drawn to a multivalent protein complex, classified in class 530, subclass 402.
  - VI. Claims 60 and 61, in so far as they are drawn to a method of treatment by administering a protein of Group I, classified in class 514, subclass 2.
  - VII. Claims 60 and 61, in so far as they are drawn to a method of treatment by administering a protein of Group II, classified in class 514, subclass 2.
  - VIII. Claim 86, drawn to a method for altering the growth state of a cell comprising contacting the cell with a lipophilic-modified hedgehog polypeptide, classified in class 514, subclass 2, for example.

The inventions are distinct, each from the other because of the following reasons:

The proteins that are inventions I, II and V are three structurally and functionally different chemical compounds, each of which can be made and used without any one or more of the other compounds. Inventions I, II and V are related in that they are proteins that require hydrophobic modification, however the proteins of invention II require spacers and the proteins of invention III are multivalent, and both the functions and the methods of making these proteins would be different, having different method steps, starting products and goals.

The method of invention IV and each of inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). The method can be used to make either of the patentably distinct products of Groups I and II, or alternatively Groups I and II do not require modification of a physio-chemical property.

The method of invention III and invention V are also related as process of making and product made. In the instant case, the method used could generate a monovalent protein.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the hydrophobically modified proteins of Group I can be used in

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the method of generating a multivalent protein of Group III, but the Group I proteins may also be used in a method of therapy, as in invention VI.

Inventions I, II and each of inventions VI, VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein may be used in a method of identifying a compound that binds to it, as well as in the therapeutic method of invention VI and VII or the method of altering cell group of invention VIII, which are materially different methods.

Invention IV and each of inventions III, VI, VII and VIII are related as method of making a product and using that product in another method. In the instant case, the method of hydrophobically modifying a protein of invention IV to produce the protein of invention I can be used in the method of generating a multivalent protein complex of invention III, but the protein product can also be used in a method of treatment, as in inventions VI and VII, or in a method of affecting cell growth as in invention VIII. The different methods have different starting points, method steps and goals.

Invention II and invention III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The spacer-containing protein of invention II is not required for or used in the method of making a multivalent protein.

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Invention V and each of inventions IV, VI, VII and VIII are unrelated. The multivalent protein of invention V is not made by or used in these methods.

Inventions III, VI, VII and VIII are unrelated. The different methods have different starting points, method steps and goals.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the need for non-coextensive literature search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara whose telephone number is (703) 308-3312. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.  
November 22, 2001

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned above the printed name and title.

LORRAINE SPECTOR  
PRIMARY EXAMINER